At-a-Glance

Proposal for Adolescent Classification Exception for Pediatric Lung Candidates

- **Affected Policies:** Policy 10.1.D: Candidates at Least 12 Years Old – LAS; Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old; Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher; Policy 10.2.B: Lung Candidates with Exceptional Cases; and Policy 10.2.B.i: LRB Review Process

  Thoracic Organ Transplantation Committee

  On June 10, 2013, the OPTN/UNOS Executive Committee approved a temporary policy permitting lung candidates less than 12 years old to request an exception from the Lung Review Board (LRB) to be classified as an adolescent candidate for the purposes of prioritization by lung allocation score (LAS). Unless further action is taken by the Board of Directors, the "adolescent classification exception" will expire on July 1, 2014. Because the temporary policy permits young pediatric lung candidates who may be suitable for lung offers from larger donors to apply for an exception, the Thoracic Committee proposes removing the July 1, 2014, deadline from the policy, making some modifications to the temporary policy, and making a permanent policy change. The Thoracic Committee also proposes additional language to clarify the data reporting requirements for candidates with approved adolescent classification exceptions.

- **Affected Groups**
  Directors of Organ Procurement
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Lung Transplant Candidates
  Lung Review Board Members
  General Public

- **Number of Potential Candidates Affected**
  As of December 6, 2013, there are 1,611 lung candidates on the waiting list. This policy has the potential to affect all of these lung candidates, as a single patient with an adolescent classification exception could impact the prioritization for every potential transplant recipient on every lung match run from donors who are 12 years and older.

  Pediatric lung candidates younger than 12 years old stand to benefit the most from these policy changes. As of December 6, 2013, there were four pediatric lung candidates less than 12 years old waiting who have already received an adolescent classification exception, and an additional 21 pediatric lung candidates less than 12 years old who were eligible to apply for the adolescent classification exception.

- **Compliance with OPTN Strategic Plan and Final Rule**

This proposal promotes §121.4 of the Final Rule, which states: “(a) The OPTN Board of Directors shall be responsible for developing policies within the mission of the OPTN including (6) Policies on such other matters as the Secretary directs.” This proposal also promotes § 121.8 of the Final Rule which states: “Allocation of organs. (a) Policy development (5) Shall be designed to promote patient access to transplantation,” and furthers the OPTN Strategic Plan of increasing access to transplant by providing an opportunity for uniquely situated pediatric candidates to access an older and larger donor pool.

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Thoracic Organ Transplantation Committee

Public comment response period: March 14, 2014 – June 13, 2014

Summary and Goals of the Proposal

On June 10, 2013, the OPTN/UNOS Executive Committee approved a temporary policy permitting lung candidates less than 12 years old to request an exception from the Lung Review Board (LRB) to be classified as an adolescent candidate for the purposes of prioritization by lung allocation score (LAS). Unless further action is taken by the Board of Directors, the "adolescent classification exception" will expire on July 1, 2014. Because the temporary policy permits young pediatric lung candidates who may be suitable for lung offers from larger donors to apply for an exception, the Thoracic Committee proposes removing the July 1, 2014 deadline from the policy, making some modifications to the temporary policy, and making a permanent policy change. The Thoracic Committee also proposes additional language to clarify the data reporting requirements for candidates with approved adolescent classification exceptions.

The Thoracic Committee hopes to continue increased access to organs by providing an opportunity for uniquely situated pediatric candidates to gain increased priority for an older and larger donor pool, thereby reducing the rate of waiting list mortality for pediatric candidates.

Background and Significance of the Proposal

The OPTN/UNOS Board of Directors approved the original LAS system in June 2004. The Thoracic Committee developed the LAS system with the goal of allocating lungs based on medical urgency, while balancing waiting list mortality and one-year post-transplant survival. Candidates within a geographic zone are prioritized for lung offers primarily by their LAS (highest to lowest). The LAS system divides candidates less than 18 into two groups: adolescents (candidates that are at least 12 years old but less than 18 years old); and pediatrics (candidates that are less than 12 years old). Candidates that are at least 12 years old are prioritized by LAS.

The LAS was developed based on candidates 12 years and older, and could not be validated for pediatric candidates younger than 12 years old.[1] The LAS system initially established a preference for allocating lungs from pediatric donors to pediatric candidates. In June 2008, the Board further refined pediatric lung allocation policy by approving a "simple status system for young pediatric candidates (based on objective medical characteristics) to direct donor lungs to the sickest of these candidates first."[2] Young pediatric lung candidates are divided into two tiers: Priority 1, for the most urgent candidates, and Priority 2. A candidate's waiting time at a priority determines the candidate's place on a match run amongst the other candidates in the same

[1] March – June 2004 Public Comment Proposal: Allocation of Lungs: Proposed Amended OPTN/UNOS Policy 3.7.6 (Status of Patients Awaiting Lung Transplantation), Policy 3.7.9 (Time Waiting for Thoracic Organ Candidates), Policy 3.7.9.2 (Waiting Time Accrual for Lung Candidates with Idiopathic Pulmonary Fibrosis (IPF)), and Policy 3.7.11 (Allocation of Lungs).
[2] June 2008 Briefing Paper: Proposal To Change Allocation of Pediatric Lungs and Allow Creation of a Stratified System for 0-11 Year-Old Candidates (Modifying Policies 3.7.6.2 (Candidates Age 0-11), 3.7.11 (Sequence of Adult Donor Lung Allocation) and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation).

priority and same geographic zone. Transplant programs can request an exception from the Lung Review Board (LRB) to register candidates as Priority 1 if they do not meet the criteria listed in policy. But, prior to June 2013, candidates registered as Priority 1 could not apply for any additional priority.

Prioritization on the match run is dependent on the age of the donor. Candidates from each age group (adult, adolescent, and young pediatric) can appear on the match run for donors of any age, but the donor's age dictates the order in which the candidate age groups appear (Figure 1). Lungs from donors 18 and older are allocated in order of LAS to all candidates aged 12 and older within the same geographic zone, and then to all candidates less than 12 in order of priority and waiting time within the same geographic zone. Lungs from adolescent donors are offered first to adolescent candidates in order of LAS within a geographic zone, then to pediatric candidates in order of priority and waiting time within the geographic zone, and finally to adult lung candidates in order of LAS within the same geographic zone. Finally, lungs from pediatric donors are first offered to pediatric candidates in order of priority and waiting time within a geographic zone, then to adolescent candidates in order of LAS within the geographic zone, and then to adult candidates in order of LAS within the geographic zone.

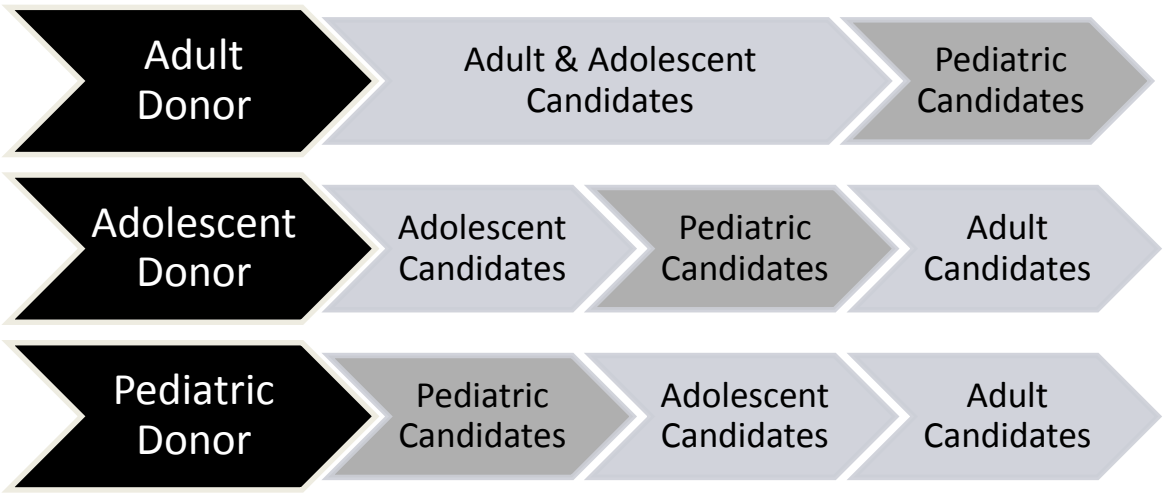

Figure 1: Allocation of Lungs Based on Donor Age Within the Same Geographic Zone

On May 31, 2013, Secretary of Health and Human Services, Kathleen Sebelius, requested that the OPTN "review the OPTN lung allocation policy as soon as possible." As part of the review, Sec. Sebelius asked that the OPTN "pay particular attention to the age categories used in lung allocation, and review the policy with the intent of identifying any potential improvements to this policy that would make more transplants available to children, consistent with the requirements of the OPTN final rule to ensure equity in organ allocation while balancing best use of donor organs."[3]

On June 10, 2013, the OPTN/UNOS Executive Committee approved changes to Policy 3.7.6.4.[4] The policy changes permit pediatric lung transplant candidates to request approval from the LRB to be classified as an adolescent candidate, in addition to being classified as a pediatric candidate,

[3] May 31, 2013, Letter from U.S. Department of Health and Human Services Secretary Kathleen Sebelius to Dr. John Roberts, President of the OPTN Board of Directors

[4] On November 15, 2013, the OPTN/UNOS Board of Directors approved a comprehensive rewrite of OPTN/UNOS policies, which involved organizational changes as well as plain language changes. As of February 1, 2014, Policy 3.7.6.4 became Policy 10.2.B: *Lung Candidates with Exceptional Cases*.

for the purposes of allocation. Candidates with approved adolescent classification exceptions appear on the match run, prioritized by LAS, with all other adolescent candidates. For offers from pediatric donors, candidates with approved adolescent classification exceptions still appear on the match run with other pediatric candidates, ordered by priority and waiting time. The policy change became effective immediately when it was passed by the Executive Committee on June 10, 2013, and has an expiration date of July 1, 2014.[5]

Following a public meeting to discuss the policy change, the Executive Committee imposed an expiration date on the policy change due to the time-sensitive circumstances requiring the change and to permit further study and collection of relevant data. The Executive Committee also approved a resolution stating "the Thoracic Organ Transplantation and Pediatric Transplantation Committees are hereby directed to review the OPTN lung allocation policy with a focus on objective medical evidence to support classifications used in lung allocation with the intent of identifying any potential improvements to the lung allocation policies for the equitable allocation of lungs that would make more transplants available to children, consistent with the requirements of NOTA and the OPTN final rule while balancing the best use of donor organs."[6]

The Thoracic Committee considered allowing the adolescent classification exception to expire on July 1, 2014. The Thoracic Committee did not pursue this approach because the policy would revert to the pre-June 10, 2013 version, which the Executive Committee previously determined was not acceptable. In addition, the Thoracic Committee recognized that the revised policy benefits select pediatric candidates who are of appropriate size to accept lungs from bigger donors, or who might be able to accept reduced sized lungs from adult donors (e.g. through lobar transplantation). The Thoracic Committee also noted that now that the exception is in place, it is best to allow it to remain in order to collect data on candidates who apply for the exception. Once ample data are collected, the Thoracic Committee can perform a more thorough analysis of its effectiveness, and the data may allow the Committee to begin to understand the relevance of the LAS in the pediatric population. The data may also help the Thoracic Committee develop a LAS suited for pediatric candidates. Literature published subsequent to the Thoracic Committee's review supports the continuation of the adolescent classification exception.[7]

The Thoracic Committee also considered permitting the exception to be automatic, rather than requiring LRB approval for each request. Though this approach would remove all measures of subjectivity from the exception process, the Thoracic Committee determined the requests should still be submitted to the LRB for approval. Requiring LRB approval results in more data collected for the Thoracic Committee's analysis, and also dissuades transplant programs from applying for the adolescent classification exception for candidates for whom lungs from older, larger candidates would not be suitable.

The Thoracic Committee discussed removing the Priority 1/Priority 2 classifications from policy and instead listing all candidates according to LAS. But, the LAS cannot be verified for candidates less than 12. Such candidates tend to have different disease processes than candidates aged 12 and older. Additionally, due to the very small number of pediatric lung candidates and even smaller number of pediatric lung transplants each year, there are not enough data to determine whether the LAS is an appropriate and accurate indicator of the waiting list and post-transplant mortality rates of candidates less than 12.

[5] June 11, 2013 Policy Notice: Summary of actions taken at June 10, 2013, OPTN/UNOS Executive Committee Meeting
[6] June 10, 2013 Minutes of the OPTN/UNOS Executive Committee Meeting
[7] Barr, M.L. and Sweet, S.C. (2014), Editorial: Pediatric Lung Allocation: The Rest of the Story, American Journal of Transplantation, 14: 11-12. DOI: 10.1111/ajt.12546

There are several potential unintended consequences of this proposal. Candidates less than 12 may receive an LAS that is not truly representative of waitlist and post-transplant outcomes (since the LAS was not validated in this age group) and thus might receive an LAS that is higher than an adult candidate with a poorer waitlist outcome. This could disadvantage select adult candidates. There are likely to be more missing values reported for the LAS calculation for adolescent classification exception candidates since the LAS was designed for implementation in the adult and adolescent populations.[8] This may further decrease the validity of the LAS for pediatric candidates.

Another unintended consequence may be poorer outcomes for pediatric candidates under 12 with approved adolescent classification exceptions who are transplanted with a lung from a donor aged 12 or older. If these candidates are prioritized for lungs from larger donors, their transplant surgeons may accept and transplant lungs that are larger than the lungs the surgeon would typically transplant in a candidate less than 12 years old. It was noted in Thoracic Committee's discussions that the outcomes of transplantation of lobes or reduced-sized lungs from adults into children less than 12 years is unknown, with few reports available in the literature.[9] Therefore, the outcomes for pediatric candidates may be affected, and could even be worse as a result of this policy change. Poorer outcomes could also potentially increase the re-transplant rate for these recipients. Finally, it was noted that candidates with an approved adolescent classification exception would have access to pediatric and adult organs, and it could be argued that this could disadvantage adult candidates with comparable LASs.

The adolescent classification exception eases the rigidity of pediatric lung allocation policy to provide an exception for those candidates that may be better served by a lung transplant from a larger donor. The proposal benefits suitable pediatric lung candidates by providing them with the ability to access a broader pool of lung donors, and should therefore exist beyond the July 1, 2014. The Pediatric Committee is supportive of the Thoracic Committee's recommendation.

This proposal also ensures that policy language matches the intent of the original policy approved by the Executive Committee regarding adolescent classification exceptions are implemented. Specifically, the proposed policy change would modify Policy 10.2.B to make clear how candidates with approved adolescent classification exceptions will be treated for offers from donors in all three age groups (i.e., such candidates will be treated as adolescents for purposes of offers from adult and adolescent donors and will be treated as children for purposes of offers from donors under 12 years of age).

[8] OPTN/UNOS Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old, requires transplant programs to report "clinical data corresponding to the covariates show in in *Table 10-2: Factors Used to Predict Risk of Death* and *Table 10-3: Factors that Predict Survival After Transplant*." Among those covariates is "six-minute walk distance" in Table 10-2. Some young pediatric candidates, most obviously infants, are not capable of performing a six-minute walk, and therefore this variable could not be reported.

[9] Examples of available studies include: Benden, C., Inci, I., Weder, W. and Boehler, A. (2010), Size-reduced lung transplantation in children – an option worth to consider!. Pediatric Transplantation, 14: 529–533. doi: 10.1111/j.1399-3046.2009.01267.x; Dominic T. Keating, Silvana F. Marasco, Justin Negri, Donald Esmore, Jacquie H. Burton, Anne P. Griffiths, Mark Buckland, Glen P. Westall, Trevor J. Williams, Gregory I. Snell, Long-term outcomes of cadaveric lobar lung transplantation: Helping to maximize resources, The Journal of heart and lung transplantation : the official publication of the International Society for Heart Transplantation 1 April 2010 (volume 29 issue 4 Pages 439-444 DOI: 10.1016/j.healun.2009.09.014); Mueller, C., Hansen, G., Ballmann, M., Schwerk, N., Simon, A. R., Goerler, H. and Strueber, M. (2010), Size reduction of donor organs in pediatric lung transplantation. Pediatric Transplantation, 14: 364–368. doi: 10.1111/j.1399-3046.2009.01242.x

On January 28, 2014, the Thoracic Committee voted by email in favor of sending the proposal for public comment: 21 approve, 0 disapprove, 0 abstentions.

Supporting Evidence and/or Modeling

Prior to the approval of the adolescent classification exception in June 2013, the Thoracic Committee, the Pediatric Committee, the Ethics Committee, and the Executive Committee reviewed data on supply and demand in lung transplantation since the implementation of the priority system in September 2010. Recently published analysis is consistent with the data the committees reviewed.[10]

On May 31, 2013, there were 20 candidates less than 12 years old actively waiting on the waiting list: eight were 0-5 years old and 12 were 6-11 years old. As compared with the pediatric candidates, there were 16 adolescent candidates between the ages of 12-17 actively waiting. When compared to adults, pediatric candidates made up a very small percentage of new lung registrations added to waiting list and of registrations ever waiting (those added during the period and those already on the list). Since September 2010, there were 47 additions aged 0-5, 38 additions aged 6-11, 95 additions aged 12-17, and 5,936 adult candidates aged 18 or older. During the same time period, there were 64 registrations aged 0-5 ever waiting, 61 registrations aged 6-11 ever waiting, 146 registrations aged 12-17 ever waiting, and 7,656 adults ever waiting.[11]

Figure 2 reflects a measure of opportunity for transplant by summarizing the number of lung registrations that received any offer (particularly three or more offers) or accepted an offer between September 2, 2010 and March 11, 2013. By itself, the number of organ offers each candidate receives may be misleading because organs accepted on the first offer would appear as only one offer. The percentage of candidates who received at least 3 offers or accepted a lung is a better measure of how the allocation system affects opportunity for receiving organ offers. Of candidates aged 6 to less than 12 years of age who were ever actively waiting during this period, 60 percent received three or more lung offers or had accepted an offer. Approximately 77 percent of adolescent lung candidates and 86 percent of adult lung candidates actively waiting during the same period received three or more lung offers or had accepted an offer.

[10] Snyder, J. J., Salkowski, N., Skeans, M., Leighton, T., Valapour, M., Israni, A. K., Hertz, M. I. and Kasiske, B. L. (2014), The Equitable Allocation of Deceased Donor Lungs for Transplant in Children in the United States. American Journal of Transplantation, 14: 178–183. doi: 10.1111/ajt.12547

[11] June 10, 2013 Minutes of the OPTN/UNOS Executive Committee Meeting

Number of lung registrations with offers or acceptance by age, 9/12/10-3/11/13

Age	Registrations ever active	Registrations with at least 1 offer		Registrations with 3 or more offers or an acceptance		Registrations with an acceptance	
	N	N	%	N	%	N	%
0-5	54	29	53.7	27	50.0	26	48.1
6-11	49	34	69.4	29	59.2	18	36.7
12-17	115	100	87.0	88	76.5	62	53.9
18+	7,323	6,826	93.2	6,262	85.5	4,396	60.0

Notes:
- Included lung registrations with or without any other organ(s)
- Age was determined based on maximum of age at listing or age at start of period

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Figure 2: Number of Lung Registrations with Offers or Acceptance by Age, 912/10-3/11/13

Figure 3 shows the rates of removal from the waiting list for reason of "death/too sick" among lung alone candidates by age group (candidates waiting for any other organ, including those waiting for heart-lung, were excluded). The rate of death/too sick per patient year was the highest for lung alone candidates less than 6 years old at 0.31 per patient-year. The rate of death/too sick was 0.25 per patient-year for the 6-11 year old age group and 0.24 per patient-year for the 12-17 year old age group. The rates for these two age groups are similar to the adult rate of 0.23 per patient-year. The transplant rate was the highest for candidates aged 0-5, and the lowest for candidates aged 6-11.

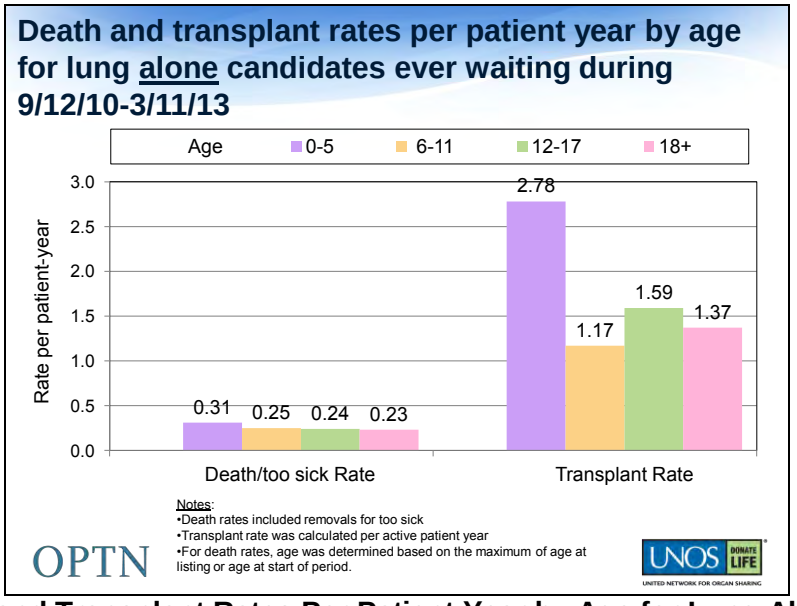

Figure 3: Death and Transplant Rates Per Patient Year by Age for Lung Alone Candidates Ever Waiting During 9/12/10 to 9/11/13

To assess whether the differences between rates of death/too sick or rates of transplant between children and adults waiting for lung alone transplants were statistically significant, the relative risk

of death/too sick and relative risk (likelihood) of transplant (as well as 95% confidence limits) were compared between pediatric and adult candidates (Figure 4). The data show that pediatric age group 6-11 and the adolescent group had almost identical risk of death/too sick as compared to adults; indeed the rates of death/too sick in any of the pediatric candidate age groups were not significantly different than those in adults. Pediatric candidates aged 0-5 years old had a significantly greater likelihood of *transplant* than adults. Pediatric candidates aged 6-11 years old had a lower likelihood of transplant, whereas candidates aged 12-17 years old had a higher likelihood of transplant compared to adults; however, neither of these differences reached statistical significance.

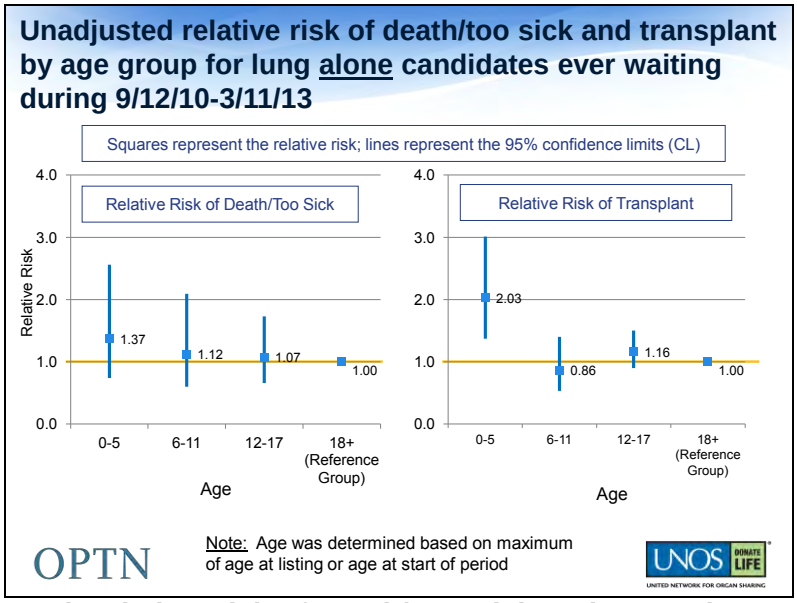

Figure 4: Unadjusted Relative Risk of Death/Too Sick and Transplant By Age Group for Lung Alone Candidates Ever Waiting During 9/12/10 to 3/11/13

The percentage of donors from whom at least one lung was transplanted varies considerably by donor age group and donor type. The percentage of deceased donors with a lung transplanted was 21% in 2011; lower than the percentage for other organs: kidney (75%), liver (74%), and heart (29%).[12] As shown in Figure 5, below, the percentage of donors from whom at least one lung was transplanted is far lower in the two youngest age groups: 4% for the youngest donors aged 0-5 and 14% for the donors aged 6-11. This is in sharp contrast to the adolescent donors, 42% of whom had at least one lung transplanted.

[12] OPTN/SRTR 2011 Annual Data Report. HHS/HRSA/HSB/DOT

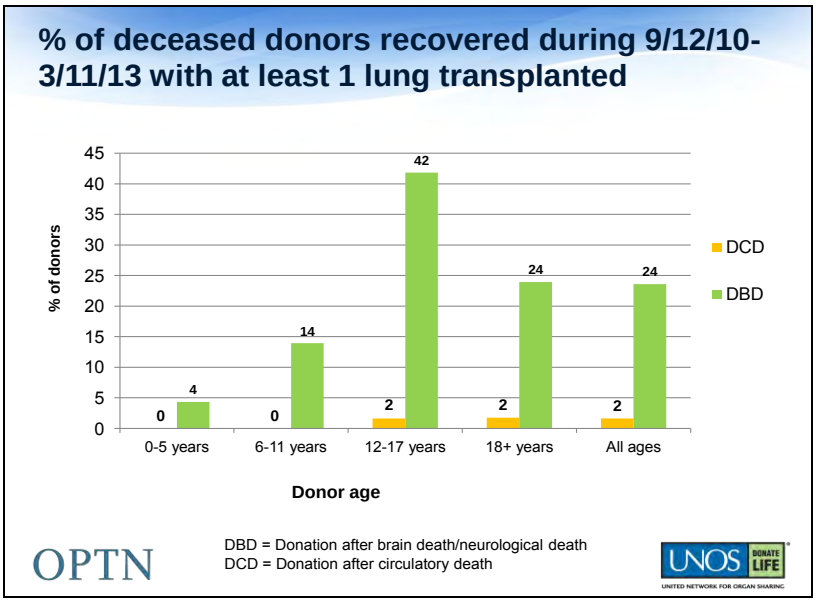

Figure 5: Percentage of Deceased Donors Recovered During Between 9/12/10 and 3/11/13 with At Least One Lung Transplanted

All lung-alone transplant recipients 0-5 years old received lungs from donors 0-5 years old. Over 60% of 6-11 year old recipients received lungs from 6-11 year old donors, and close to 40% received lungs from donors 0-5 years old. About 40% of recipients 12 to 17 years old received lungs from an adult donor, and most adult recipients received lungs from adult donors. (Figure 6). These results may be a function of donor/recipient size matching as well as the ordering of offers in the lung allocation system.

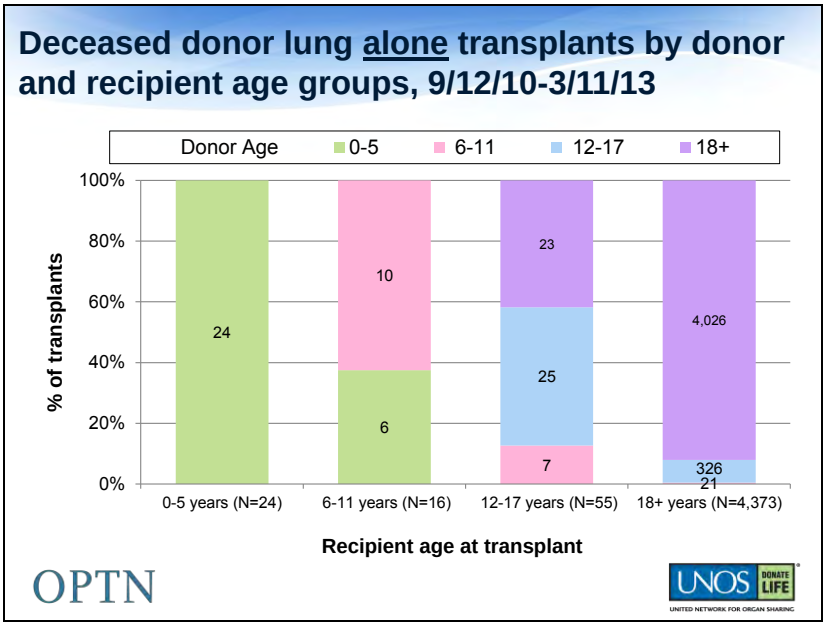

Figure 6: Deceased Donor Lung Alone Transplants By Donor and Recipient Age Groups Between 9/12/10 and 3/11/13

Finally, the one year Kaplan-Meier patient survival was the highest for 6-11 year old recipients of lung-alone transplants at 100%, and the lowest for recipients 0-5 years old and 12-17 years old at 78%, as seen in Figure 6 below.

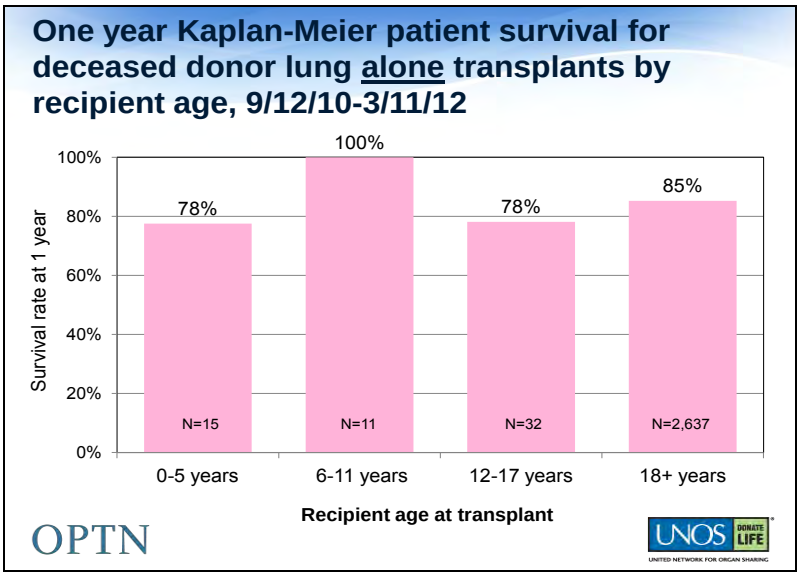

Figure 7: One Year Kaplan-Meier Patient Survival for Deceased Donor Lung Alone Transplants by Recipient Age Between 9/11/10 and 3/11/12

As of January 13, 2014, five candidates with approved adolescent classification exceptions were transplanted, four were still waiting for transplant, and one died. Of the 10 candidates with approved adolescent exceptions, seven were 10 or 11 years old at the time of the exception request, and three were between 6 and 9 years old. Six of the candidates were blood type O, two were blood type A and two were blood type B. Six of the 10 candidates were diagnosed with cystic fibrosis, two candidates had primary arterial hypertension, one candidate had ARDS/pneumonia, and one candidate had pulmonary veno-occlusive disease. After receiving LRB approval for the adolescent classification exception, four candidates also requested an LAS score exception.

The Thoracic Committee concluded that the adolescent classification exception is working as intended to potentially broaden access to donors for candidates less than 12 years old. The majority of candidates requesting the exception were between 10 and 11 years old, and none of the requestors were younger than six. The data reviewed by the Executive Committee revealed that the probability of transplant within 12 months of listing was lowest for candidates between 6 and 11 years old waiting for a lung alone transplant. Therefore, the adolescent classification exception is thus far being utilized by the candidates most in need of the exception.

Expected Impact on Living Donors or Living Donation

This policy has potential to impact living lung donation. If young pediatric candidates have access to a broader pool of donors, the demand for living lung donors may change.

Expected Impact on Specific Patient Populations

This proposal is intended to have the greatest impact on pediatric lung transplant candidates by providing them with increased access to a broader pool of lung donors. This proposal is most

likely to benefit pediatric candidates 6-11 years old, as they are the candidates most likely to request an adolescent classification exception. Lung transplant candidates older than 12 may also be impacted because more candidates may be included in the adolescent age group for purposes of allocation.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule

This proposal promotes §121.4 of the Final Rule, which states: "(a) The OPTN Board of Directors shall be responsible for developing policies within the mission of the OPTN including (6) Policies on such other matters as the Secretary directs." On May 31, 2013, the Secretary of Health and Human Services, Kathleen Sebelius, directed the OPTN to "initiate a process to review the OPTN lung allocation policy as soon as possible," and to "pay particular attention to the age categories currently used in lung allocation, and review the policy with the intent of identifying any potential improvements to this policy that would make more transplants available to children, consistent with the requirements of the OPTN final rule to ensure equity in organ allocation while balancing best use of donor organs."

This proposal also promotes § 121.8 of the Final Rule, which states: "Allocation of organs. (a) Policy development. (5) Shall be designed to promote patient access to transplantation," and furthers the OPTN Strategic Plan of increasing access to transplant by providing an opportunity for uniquely situated pediatric candidates to gain increased access to an older and potentially larger donor pool. The Thoracic Committee believes that offer rates to candidates less than 12 will increase, while waiting list mortality rates for this age group will decrease.

Plan for Evaluating the Proposal

This proposal is designed to increase access to transplant for lung candidates less than 12 years old. The evaluation of this proposal will assess whether the transplant rate has increased and the rate of waiting list mortality has decreased in this population, without adversely affecting post-transplant survival rates. As this proposal is not intended to negatively affect access for adolescents and adults, waiting list outcomes in these other age groups will also be assessed.

Due to the small number of lung candidates younger than 12 years, for the first two years the number of cases will be monitored. More detailed analysis will be initiated two years after Board approval. The analysis will be performed annually for three years.

The number of candidates that request an adolescent classification exception and the outcome of the request (approved, denied, withdrawn) will be reported, and they will be analyzed by age group, gender, ethnicity, ABO blood group, and diagnosis.

The waiting list outcome analysis will be based on all lung candidates ever waiting during a specified period following Board approval. Where possible, external data sources will be used to supplement death reporting to the OPTN.

Rates of waiting list mortality/too sick rates will be computed based on the number of deaths or removals from the waiting list for being too sick in comparison to the number of patient-years waiting during the specified time period. The rates will be stratified by candidate age group. The rates will be compared between the post-policy period and pre-policy period within each age group using a relative risk, with associated confidence limits, to determine if the rates have changed between policy periods. Rates will also be compared across age groups within each policy period using relative risks and confidence limits.

Transplant rates will be computed based on the number of transplants compared to the number of active patient-years waiting during the specified time period. The rates will be stratified by candidate age group. As with the rates of mortality/too sick, comparisons of rates between policy periods and between age groups will be performed using relative risks and confidence limits.

The number of transplants for recipients younger than 12 years old in the pre- and post- policy periods will be tabulated by donor age. Post-transplant graft and patient survival rates for recipients younger than 12 years old will be computed using the Kaplan-Meier method. The rates will be compared between the pre- and post-policy periods using the log-rank test statistic. Though patient survival rates are most frequently used for post-transplant outcome assessment in lung transplants, the graft survival rates will also be provided. The graft survival rates will be used for this proposal to assess whether there has been a change in the frequency of graft failure rates in young pediatric lung recipients, thus resulting in the need for re-transplantation.

When there is a sufficient number, post-transplant graft and patient survival rates of recipients transplanted due to an approved adolescent classification exception will also be computed using the Kaplan-Meier method, and will be compared with post-transplant graft and patient survival rates of adolescent recipients who did not receive a transplant due to an approved adolescent classification exception.

Additional Data Collection

This proposal will only require additional data reporting for pediatric candidates with an approved adolescent classification exception, and it meets the following OPTN Data Collection Principle: "Develop transplant, donation, and allocation policies." Transplant programs will be responsible for reporting the same data for candidates with an approved adolescent classification exception as all other candidates aged 12 and older, as listed in OPTN Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old. This proposal does not require any data fields to be added to Waitlist[SM].

If a transplant program does not submit data for each required LAS variable, or if a value expires, policy provides default values that will automatically substitute for the missing value. The Thoracic Committee proposes using the same default values for candidates with an approved adolescent classification exception as are used for candidates aged 12 and older. Also, transplant physicians can request LRB approval of estimated values, or estimated LAS, if the physicians cannot perform the tests to obtain required values, or do not believe the policy default values or calculated LAS appropriately reflect the candidate's condition.

The data submitted will be valuable to the Thoracic Committee in its effort to improve the lung allocation policy for all age groups. Collecting the same data for candidates with approved adolescent classification exceptions as is collected for candidates 12 years and older will provide the OPTN with more robust data on candidates less than 12, and allow the Thoracic Committee to more accurately analyze and classify these candidates and ensure they have equitable access to transplant. This may facilitate future development of an appropriately validated LAS for children, rather than relying on a model developed and validated for an older population.

Expected Implementation Plan

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in June, 2014. If these policy changes are adopted by the Board of Directors, members will be notified with the Policy Notice following that Board of Directors' meeting. This proposal will require programming in UNet[SM], but the policy will be effective immediately upon approval. Until programming can occur, applications to the LRB for the adolescent classification exception will be processed manually, following current practice. Transplant programs should re-read the memo first distributed on August 26, 2013, "Recommendation for Submitting Information and Evidence in Support of Lung Review Board (LRB) Exception Requests."

Prior to programming, transplant programs will be responsible for maintaining two registrations for candidates with an approved adolescent classification exception (though transplant programs will not be charged an additional registration fee for the second registration). The UNOS Review Board Staff provides instructions for maintaining the candidate's second record in the email sent to the transplant program providing notification of the LRB's approval.

Until programming is complete, UNOS staff will continue to track and monitor these records manually. When programming is complete, members will receive UNet℠ System Notices approximately 30 days prior to implementation, as well as on the day of implementation.

Communication and Education Plan

This policy change only affects lung programs and a very small subset of lung patients. Since a high-profile media case served as the catalyst for the initial policy change, very general information about the removal of the temporary status needs to be communicated much more broadly than specifics about the data collection requirements. Since less than 10 transplant hospitals perform pediatric lung transplants nationally, we may want to consider direct communications with those centers regarding instructions for the exception process going forward.

If approved, notification of the policy modification will be included in the following routine communication vehicles:

- Policy notice
- System notice
- UNOS Update article
- E-newsletter/member archive article
- Presentation at Regional Meetings
- Formal training (e-modules, Live Meetings, Webinars, etc.)
- Articles/Guidance Documents on the Web and Member Archive

Compliance Monitoring

UNOS will continue to review a sample of recipient medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet^{SM} is consistent with source documentation, including data reported on the LRB application and in UNet^{SM}.

Policy or Bylaw Proposal

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

10.1.D Candidates at Least 12 Years Old - LAS

Candidates who are at least 12 years old or who have an approved adolescent classification exception receive offers for deceased donor lungs based on their calculated LAS. Candidates with a higher LAS receive higher waiting list priority within geography and blood type classifications.

10.1.E LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old

When registering a candidate who is at least 12 years old for a lung transplant, or when registering a candidate with an approved adolescent classification exception according to *Policy 10.2.B: Lung Candidates with Exceptional Cases*, transplant programs must report to the OPTN Contractor clinical data corresponding to the covariates shown in *Table 10-2: Factors Used to Predict Risk of Death* and *Table 10-3: Factors that Predict Survival after Lung Transplant*.

The data reported at the time of the candidate's registration on the lung transplant waiting list must be six months old or less from the date of the candidate's registration date. The transplant

program must maintain source documentation for all laboratory values reported in the candidate's medical chart.

Except as noted in *Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher*, transplant programs must report to the OPTN Contractor LAS covariate clinical data for every covariate in *Table 10-2* and *Table 10-3* for each candidate at least once in every six month period after the date of the candidate's initial registration or the LRB's approval of an adolescent classification exception. The first six-month period begins six months from the date of the candidate's initial registration, or, in the case of adolescent classification exceptions, six months from the date of the LRB approval, with a new six-month period occurring every six months thereafter.

A covariate's value expires if the covariate's test date is six-months older than the most recent six-month anniversary date. The LAS system considers actual values and approved estimated values for pulmonary pressures to be valid until the transplant program updates them with new actual values or new approved estimated values as described in Policy *10.2.B.iii: Estimated Values Approved by the LRB*.

Transplant programs may report a medically reasonable estimated value if a test needed to obtain an actual value for a variable covariate cannot be performed due to the candidate's medical condition. Before entering estimated values, programs must receive approval from the LRB, which will determine whether the estimated values are appropriate according to *Policy 10.2.B.iii: Estimated Values Approved by the LRB.* Approved estimated values remain valid until an updated actual value is reported for the covariate, or until the transplant program reports a new, approved estimated value.

LAS covariate data obtained by heart catheterization does not need to be reported to the OPTN Contractor every six months. For LAS covariate data that requires a heart catheterization, the transplant program may determine the frequency of updating the data. However, if a transplant program performs a heart catheterization test on the candidate during the six month interval, then it must report the data to the OPTN Contractor.

Candidate clinical data corresponding to the variables shown in Tables *10-2* and *10-3* must be reported to the OPTN Contractor when listing a candidate for lung transplant. Diagnosis, birth date (used to calculate age), height and weight (used to calculate BMI) must be entered for a candidate to be added to the waitlist. Candidates will receive a LAS of zero if the functional status class or assisted ventilation variable is missing a value at any time.

If values for pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure are missing, then a default value will be assigned that represents a normal clinical value for these missing pulmonary pressure variables. A default value of 20 mm Hg will be assigned for missing pulmonary artery systolic pressure, a default value of 5 mm Hg will be assigned for missing pulmonary capillary wedge pressure, and a default value of 15 mm Hg will be assigned for missing pulmonary artery mean pressure. The default values for pulmonary pressures will also be used in the calculation of LAS for those candidates whose actual values are provided, but are lower than the default value. If any other candidate variables are missing, then a default value, which will be the value that results in the lowest contribution to the LAS for that variable field ("Least Beneficial Value"), will be selected for the candidate.

Transplant programs are permitted to enter a value deemed medically reasonable in the event a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a specific candidate. Prior to entering such estimated values, programs must request review and approval from the Lung Review Board (LRB) to determine whether the estimated values are appropriate. Estimated values will remain valid until those values are either updated with an actual value or a new estimated value is entered according to this Policy.

10.2.B Lung Candidates with Exceptional Cases

The Thoracic Organ Transplantation Committee establishes guidelines for special case review by the LRB.

If a candidate's transplant program believes that a candidate's current priority or LAS does not appropriately reflect the candidate's medical urgency for transplant, the transplant program may request approval of a specific priority or LAS by the LRB. The transplant program can also ask the LRB to approve specific estimated values or diagnoses.

For lung candidates less than 12 years old, transplant programs may request classification as an adolescent candidate for the purposes of *Policy 10.4.C: Allocation of Lungs from Deceased Donors at Least 18 Years Old*, and *Policy 10.4.D: Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old*. Candidates receiving this exception will also maintain their pediatric classification for the purposes of *Policy 10.4.E: Allocation of Lungs from Deceased Donors Less than 12 Years Old*.

10.2.B.i LRB Review Process

Requests for approval of estimated values, diagnoses, ~~or~~ specific LAS, or adolescent classification exceptions require prospective review by the LRB. The transplant hospital must submit requests for LRB review to the OPTN Contractor, and accompany each request for special review with a supporting narrative. The LRB will have seven days to reach a decision regarding the request, starting from the date that the OPTN Contractor sends the request to the LRB.

If the LRB denies a request upon initial review, then the transplant program may choose to appeal the decision and request reconsideration by the LRB. The transplant program has seven days from the date of the initial denial of the initial request to appeal. The LRB has seven days to reach a decision on the appeal, starting from the date that the OPTN Contractor sends the appealed request to the LRB. If the LRB does not complete its review of an initial request or appeal within seven days of receiving it, then the candidate will not receive the requested LAS, diagnosis, estimated value, or adolescent classification, and the OPTN Contractor will send the request or appeal to the Thoracic Organ Transplantation Committee for further review.

Requests to register a candidate less than 12 years old as priority 1 require retrospective LRB review by the LRB.